



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Headquarters organizations, and Centers have modified their structures.

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SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970; 60 FR 56606, November 9, 1995; 64 FR 36361, July 6, 1999; 72 FR 50112, August 30, 2007; 74 FR 41713, August 18, 2009; and 76 FR 45270, July 28, 2011) is amended to reflect the reorganization of the Office of the Commissioner/FDA Headquarters and the following Centers: Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), Center for Food Safety and Applied Nutrition (CFSAN), Center for Tobacco Products (CTP), and Center for Veterinary Medicine (CVM).

The Office of the Commissioner reorganization will transition FDA away from the Directorate structure. Abolishing the current directorate structure and realigning many of those

functions to the Centers/Office of Regulatory Affairs (ORA) establishes a direct line of communication between the Centers/ORA and the Commissioner of Food and Drugs. This direct report relationship with the Centers streamlines communications and better positions FDA to support its regulatory programs and mission. The intent is to create a more effective structure that better reflects FDA's priorities and streamlines operations.

The CDRH reorganization will more accurately reflect the functions performed by the Center and help to enhance CDRH's ability to advance FDA's mission and streamline operations and support functions.

The CDER reorganization changes the organizational structures and revises the functional statements of following organizations: Office of Communication (OCOMM), Office of Compliance (OC), Office of Executive Programs (OEP), Office of Hematology and Oncology Products (OHOP), and Office of New Drugs (OND). The proposed organizational changes will enhance CDER's ability to develop, coordinate, and evaluate public health communication and education activities in support of the following:

The CDER Office of Compliance proposed structure change will establish the framework for a stronger regulatory oversight of the compounded human drugs facilities and compounding related activities. The new structure will help ensure the following: that compounding pharmacies operate within the bounds of traditional pharmacy practice (not manufacturing); that outsourcing facilities operate according to the conditions in section 503B; and the new structure will protect patients from unsafe or ineffective compounded drugs.

The CDER Office of Communication is planning to expand CDER's communications outreach and educational efforts to inform the conversation among FDA's stakeholders. This will be managed through accessing more communication channels, enhancing FDA's social

media presence, and using more innovative tools. The impact of CDER's growth has impacted the volume of information posted on the web as the content management and development of tools used to connect stakeholders with web content are created. As new programs and initiatives are developed by the Center, the web content will increase. The new content management system will provide the Agency with the opportunity to finally have a true publishing tool. This will allow greater speed in posting the content in the web environment.

The CDER Office of Executive Programs houses all the executive functions for CDER and ensures the goals and priorities of the Center Director are carried out. These functions range from administrative support for the Center Director's Office, overseeing the Center's learning and organizational development program, to managing the Center's 18 different Advisory Committees. Restructuring these functions into defined organizational structures will improve decision making by promoting the direct flow of information from frontline employees to the managers directly responsible for making decisions and provide clarity to staff roles and responsibilities. Furthermore, the proposed organizational changes permit Office of Executive Programs' managers to better define critical business processes and identify opportunities for streamlining complex tasks, which will facilitate a more efficient and strategic deployment of these resources during public health emergencies and outbreaks. The proposed changes align with Reimagine HHS guiding principle #3--Generating Efficiencies through Streamlined Processes and Reimagine HHS guiding principle #5--HHS as a More Innovative and Responsive Organization.

The CDER Office of Hematology and Oncology Products reorganization is in response to Title III of the 21st Century Cures Act (Cures Act), enacted into law on December 13, 2016, which provides authorities FDA can use to help modernize drug, biological, and device product

development and review to create greater efficiencies and predictability in product development and review. Numerous initiatives are currently taking place in the Agency to carry out the plan laid out in the Cures Act and include: Patient Focused Drug Development; Novel Clinical Trial Design; Real World Evidence; Summary-level Review and Inter-Center Institutes; as well as other initiatives. The Office of Hematology and Oncology Products has been an active participant and at times a leader in many of these initiatives. To meet external and internal stakeholders' expectations and to effectively and efficiently carry out these initiatives delineated in the Cures Act, it is necessary to flatten out the organizational structure. The office proposes to expand their clinical review divisions from three to five, create a centralized safety reporting team, and create a labeling team. The office is dedicated in modernizing the drug, biological, and device product development and review and in creating greater efficiencies and predictability in oncology product development and review. With this restructuring, the office, working in partnership with the Oncology Center of Excellence, can ensure that the Agency's initiatives are being worked on in an efficient and cohesive manner so that industry and all other outside groups feel as if we are working with them in the fight against cancer.

The CDER Office of Therapeutic Biologics and Biosimilars reorganization is in response to the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), which was enacted on March 23, 2010. This law amended the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to or interchangeable with an already approved FDA-licensed biological product (the reference product). This pathway was established to provide more treatment options, increase access to lifesaving medications, and potentially reduce healthcare costs through increased competition. The current review management and policy development approach for biosimilar and

interchangeable products lacks a “primary owner” and this impacts CDER’s ability to set a singular goal and focus on internal operational requirements and communication similar to new drugs and generic drugs products. Specifically, policy development is fractured between the CDER Office of Medical Policy (OMP), Office of New Drugs (OND), and Office of Regulatory Policy (ORP). Since there is no office that holds primary responsibility for setting policy direction, the drafting and responding to inquiries such as citizen petitions and the development of policy positions is split between the various organizations. Likewise, the communication efforts are split between CDER OMP, OND, and OCOMM. While there is clear evidence of operational efficiencies associated with the review process for biosimilar and interchangeable products, the biggest inefficiency is with policy development. This proposed reorganization will be part of FDA’s ongoing efforts to achieve the performance goals agreed to by the Agency in conjunction with the reauthorization of Biosimilar User Fee Act (BsUFA II).

The CFSAN reorganization realigns functions and personnel, retitling and establishing of new organizations within the CFSAN offices of: Office of Cosmetics and Colors, Office of Food Additive Safety, and Office of Coordinated Outbreak Response and Evaluation Network, which formalize its organizational components and functions; distinguish operational culture between pre- and post-market review; clarify staff allocation; improve effectiveness; and increase efficiency in the management and leadership for internal and external stakeholders.

The CTP Office of Health Communication and Education reorganization establishes the Division of Research and Evaluation; changes the title of the Division of Health, Scientific, and Regulatory Communication to the Division of Regulatory Communication; and revises the functional statements of the Office of Health Communication and Education; the Division of Public Health Education; and the Division of Regulatory Communication. The proposed

organizational changes will enhance the Center's ability to develop, coordinate, and evaluate public health communication and education activities in support of requirements of the Family Smoking Prevention and Tobacco Control Act.

The CVM reorganization affects the Center's Office of Management and Office of New Animal Drug Evaluation.

The CVM Office of Management reorganization establishes the Business Informatics Staff; abolishes the Management Logistics Staff; and revises the functional statements of the Office of Management. The organizational changes will enhance CVM's ability to promote information technology guidelines and policies; manage the center's information technology portfolio; and provide capital planning and investment controls to the Department of Health and Human Services.

The CVM Office of New Animal Drug Evaluation reorganization establishes the Division of Animal Bioengineering and Cellular Therapies and revises the functional statements of the Office of New Animal Drug Evaluation. The organizational changes will create a dedicated group for the review and approval of biologically derived emerging technologies, such as animal bioengineering and cell and gene therapy products.

The Food and Drug Administration, Office of the Commissioner (OC) and Headquarters, Centers, and Offices, have been restructured as follows:

DCA. ORGANIZATION. The Office of the Commissioner is headed by the Commissioner of Food and Drugs, and includes the following organizational units:

OFFICE OF THE COMMISSIONER

Office of the Chief Counsel

Office of the Executive Secretariat

Freedom of Information Staff

Office of the Counselor to the Commissioner

DCB. ORGANIZATION. The Center for Biologics Evaluation and Research is headed by the Center Director.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

DCC. ORGANIZATION. The Center for Devices and Radiological Health is headed by the Center Director and includes the following organizational units:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Office of the Center Director

Quality Management Staff

Office of Science and Engineering Laboratories

Management Support Staff

Division of Biomedical Physics

Division of Imaging, Diagnostics, and Software Reliability

Division of Applied Mechanics

Division of Administrative and Laboratory Support

Division of Biology, Chemistry and Materials Science

Office of Communication and Education

Program Management Operations Staff

Division of Communication

Web and Graphics Branch

External Communications Branch

Internal Communications Branch

Division of Industry and Consumer Education

Postmarket and Consumer Branch

Premarket Programs Branch

Division of Information Disclosure

Freedom of Information Branch A

Freedom of Information Branch B

Division of Employee Training and Development

Employee Development Branch

Technology and Learning Management Branch

Office of Management

Planning and Program Analysis Staff

Division of Workforce Management

Division of Financial Management

Division of Management Services

Division of Acquisition Services

Office of Product Evaluation and Quality

Quality and Analytics Staff

Clinical and Scientific Policy Staff

Strategic Initiatives Staff

Regulation, Policy and Guidance Staff

Office of Regulatory Programs

Division of Regulatory Programs I

Division of Regulatory Programs II

Division of Regulatory Programs III

Office of Clinical Evidence and Analysis

Division of Clinical Evidence and Analysis I

Division of Clinical Evidence and Analysis II

Office of Health Technology I

Division of Health Technology I A

Division of Health Technology I B

Division of Health Technology I C

Office of Health Technology II

Division of Health Technology II A

Division of Health Technology II B

Division of Health Technology II C

Office of Health Technology III

Division of Health Technology III A

Division of Health Technology III B

Division of Health Technology III C

Office of Health Technology IV

Division of Health Technology IV A

Division of Health Technology IV B

Office of Health Technology V

Division of Health Technology V A

Division of Health Technology V B

Office of Health Technology VI

Division of Health Technology VI A

Division of Health Technology VI B

Division of Health Technology VI C

Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

Chemistry Branch

Diabetes Branch

Toxicology Branch

Cardio-Renal Diagnostics Branch

Division of Immunology and Hematology Devices

Hematology Branch

Immunology and Flow Cytometry Branch

Division of Microbiology Devices

Viral Respiratory and Human Papilloma Respiratory Branch

General Viral and Hepatitis Branch

General Bacterial and Antimicrobial Susceptibility Branch

Bacterial Respiratory and Medical Countermeasures Branch

Division of Radiological Health

Magnetic Resonance and Electronic Products Branch

Diagnostic X-Ray Systems Branch

Nuclear Medicine and Radiation Therapy Branch

Mammography, Ultrasound and Imaging Software Branch

Division of Mammography Quality Standards

Program Management Branch

Information Management Branch

Division of Program Operations and Management

Division of Molecular Genetics and Pathology

Molecular Pathology and Cytology Branch

Molecular Genetics Branch

Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science and Strategic Partnerships

Division of Digital Health

Division of Technology and Data Services

Office of Policy

DCD. ORGANIZATION. The Center for Drug Evaluation and Research is headed by the Director and includes the following organization units:

CENTER FOR DRUG EVALUATION AND RESEARCH

Office of the Center Director

Office of Regulatory Policy

Office of Management

Office of Communications

Office of Compliance

Office of Manufacturing Quality

Office of Unapproved Drugs and Labeling Compliance

Office of Scientific Investigations

Office of Program and Regulatory Operations

Office of Medical Policy

Office of Prescription Drug Promotion

Office of Medical Policy Initiatives

Office of Translational Sciences

Office of Biostatistics

Office of Clinical Pharmacology

Office of Computational Science

Office of Study Integrity and Surveillance

Office of Executive Programs

Office of Surveillance and Epidemiology

Office of Medication Error Prevention and Risk Management

Office of Pharmacovigilance and Epidemiology

Office of New Drugs

Office of Drug Evaluation I

Office of Drug Evaluation II

Office of Drug Evaluation III

Office of Antimicrobial Products

Office of Drug Evaluation IV

Office of Hematology and Oncology Products

Office of Strategic Programs

Office of Program and Strategic Analysis

Office of Business Informatics

Office of Generic Drugs

Office of Research Standards

Office of Bioequivalence

Office of Generic Drug Policy

Office of Regulatory Operations

Office of Pharmaceutical Quality

Office of Biotechnology Products

Office of New Drug Products

Office of Policy for Pharmaceutical Quality

Office of Process and Facilities

Office of Surveillance

Office of Testing and Research

Office of Program and Regulatory Operations

Office of Lifecycle Drug Products

DCE. ORGANIZATION. The Center for Food Safety and Applied Nutrition is headed by the Center Director.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

DCED. ORGANIZATION. The Office of Food Additive Safety is headed by the Director, Office of Food Additive Safety, and includes the following organizational units:

Office of Food Additive Safety

Operations Staff

Division of Food Contact Substances

Toxicology Review Branch

Chemistry Review Branch

Regulatory Review Branch

Division of Food Ingredients

Toxicology Review Branch

Chemistry Review Branch

Regulatory Review Branch

Division of Biotechnology, Regulatory Science, and Surveillance

Post-Market Review Branch

Scientific Support Branch

DCEE. ORGANIZATION. The Office of Cosmetics and Colors is headed by the Director, Office of Cosmetics and Colors, and includes the following organizational units:

Office of Cosmetics and Colors

Division of Cosmetics and Colors

Color Certification Branch

Color Technology Branch

Division of Cosmetics

Cosmetics Regulatory Activities Branch

Cosmetics Regulatory Science Branch

DCEN. ORGANIZATION. The Office of Coordinated Outbreak Response and Evaluation Network is headed by the Director, Office of Coordinated Outbreak Response and Evaluation Network, and includes the following organizational units:

Office of Food Additive Safety

Signals and Analysis Staff

DCF. ORGANIZATION. The Center for Tobacco Products is headed by the Center Director.

CENTER FOR TOBACCO PRODUCTS

DCFF. ORGANIZATION. The Center for Tobacco Products Office of Health Communication and Education is headed by the Director of Health Communication and Education and includes the following organizational units:

Office of Health Communication and Education

Division of Public Health Education

Division of Regulatory Communication

Division of Research and Evaluation

DCG. ORGANIZATION. The Center for Veterinary Medicine is headed by the Center Director.

CENTER FOR VETERINARY MEDICINE

DCGB. ORGANIZATION. The Center for Veterinary Medicine Office of Management is headed by the Associate Director for Management and includes the following organizational units:

Budget Planning and Evaluation Staff

Business Informatics Staff

Human Capital Management Staff

Program and Resources Management Staff

Talent Development Management Staff

DCGC. ORGANIZATION. The Center for Veterinary Medicine Office of New Animal Drug Evaluation is headed by the Director of New Animal Drug Evaluation and includes the following organizational units:

Division of Animal Bioengineering and Cellular Therapies

Division of Business Information Science and Management

Division of Generic Animal Drugs

Division of Human Food Safety

Division of Manufacturing Technologies

Division of Production Drugs

Division of Scientific Support

Division of Therapeutic Drugs for Food Animals

Division of Therapeutic Drugs for Non-Food Animals

DCH. ORGANIZATION. The Oncology Center of Excellence is headed by the Director and includes the following organizational units:

ONCOLOGY CENTER OF EXCELLENCE

DCI. ORGANIZATION. The Office of Regulatory Affairs is headed by the Associate Commissioner for Regulatory Affairs.

OFFICE OF REGULATORY AFFAIRS

DCJ. ORGANIZATION. The Office of Clinical Policy and Programs is headed by the Director, Office of Clinical Policy and Programs, and includes the following organizational units:

OFFICE OF CLINICAL POLICY AND PROGRAMS

Healthcare Provider Staff

Patient Affairs Staff

Office of Clinical Policy

Good Clinical Practice Staff

Office of Combination Products

Office of Orphan Products Development

Office of Pediatric Therapeutics

DCK. ORGANIZATION. The Office of External Affairs is headed by the Associate Commissioner for External Affairs and includes the following organizational units:

OFFICE OF EXTERNAL AFFAIRS

Operations Staff

FDA History Office

Stakeholder Engagement Staff

Web & Digital Services Staff

Office of Media Affairs

Office of Editorial and Creative Services

DCL. ORGANIZATION. The Office of Food Policy and Response is headed by the Deputy Commissioner for Food Policy and Response, and includes the following organizational units:

OFFICE OF FOOD POLICY AND RESPONSE

Office of Resource Planning and Strategic Management

DCM. ORGANIZATION. The Office of Minority Health and Health Equity is headed by the Assistant Commissioner for Minority Health and Health Equity and includes the following organizational units:

OFFICE OF MINORITY HEALTH AND HEALTH EQUITY

DCN. ORGANIZATION. The Office of Operations is headed by the Chief Operating Officer and includes the following organizational units:

OFFICE OF OPERATIONS

Office of Enterprise Management Services

Program Effectiveness Staff

Division of Compliance and Conflict Prevention

Conflict Prevention and Resolution Staff

Division of Human Capital

Division of Information Governance

Dockets Management Staff

Division of Resource Management

Division of Vendor Management

Office of Equal Employment and Opportunity

Compliance Staff

Office of Ethics and Integrity

Office of Facilities, Engineering and Mission Support Services

Jefferson Laboratories Complex Staff

Facilities Program Staff

Employee Safety and Occupational Health Staff

Division of Operations Management and Community Relations

Logistics and Transportation Management Branch

Facilities Maintenance and Operations Branch

Auxiliary Program Management Staff

Division of Planning, Engineering and Space Management

Portfolio and Space Management Branch

Engineering Management Branch

Office of Finance, Budget, and Acquisitions

Business Management Services Staff

Office of Acquisitions and Grants Services

Division of Acquisition Operations

Service Contracts Branch

Contracts Operations Branch

Division of Acquisition Programs

Scientific Support Branch

Field Operations Branch

Facilities Support Branch

Division of State Acquisitions, Agreements and Grants

Grants and Assistance Agreements Branch

ORA Inspection Branch

CTP Inspection Branch

Division of Information Technology Acquisitions

Information Technology Acquisitions Branch

Systems Technology Acquisitions Branch

Information Technology Strategic Support Branch

Division of Policy, Systems and Program Support

Training and Development Branch

Acquisitions Policy and Oversight Branch

Office of Budget

Division of Budget Formulation and Program Alignment

Division of Budget Execution and Control

Office of Financial Management

Financial Systems Support Staff

Division of Accounting

Division of Controls, Compliance and Oversight

Division of Payment Services

Division of Travel Services

Field Operations Staff

Division of User Fees

Office of Human Capital Management

Business Operations Staff

Management and Administrative Inquiries Staff

Performance Management and Awards Staff

Division of FDA Training and Development

Organization Development and Learning Solutions Branch

Training Delivery and Program Operations Branch

Division of Human Resources Systems and Operations Support

Data Quality and Services Management Branch

Human Resources Information Systems and Records Branch

Human Resources Information Technology Branch

Retirement and Benefits Branch

Timekeeping and Payroll Services Branch

Division of Employee and Labor Relations

Employee Relations Branch I

Employee Relations Branch II

Labor Relations Branch

Division of Strategic Talent Management Programs

Workforce Support and Development Branch

Quality of Work-life Programs Branch

Office of Information Management and Technology

Office of Information Management

Office of Information Security

Office of Technology and Delivery

Delivery Management and Support Staff

Division of Infrastructure Operations

Infrastructure Management Services Staff

Implementation Branch

Infrastructure Engineering Branch

Systems Monitoring & Response Branch

Systems Operations Branch

Network & Communications Operations Branch

Division of Application Services

Application Management Services Staff

Data Management & Operations Branch

Medical Products Branch

OC/CVM/CTP Branch

ORA/CFSAN Branch

Enterprise Applications Branch

Office of Business & Customer Assurance

Division of Business Partnership & Support

Internet & Intranet Branch

Call Center Branch

Regional Support Branch

Property, Receiving & Distribution Branch

Employee Resource and Information Center

Division of Management Services

Office of Enterprise Portfolio Management

Office of Informatics & Technology Innovation

Informatics Staff

Knowledge Management Staff

Enterprise Architecture Staff

Office of Planning and Evaluation

Planning Staff

Program Evaluation and Process Improvement Staff

Office of Security and Emergency Management

Office of Security Operations

Office of Emergency Management

Emergency Planning, Exercises and Evaluation Staff

Program Operations and Coordination Staff

Office of Emergency Operations

Office of Talent Solutions

Commission Corps Staff

Executive Resources Staff

Policy and Accountability Staff

Scientific Talent Recruitment Staff

Division of Talent Services I

CDER Branch A

CDER Branch B

CDER Branch C

Division of Talent Services II

CFSAN and CVM Branch

OC and National Center for Toxicological Research Branch

OO Branch

Division of Talent Services III

CBER Branch

CDRH Branch

CTP Branch

Division of Talent Services IV

ORA Branch A

ORA Branch B

ORA Branch C

Division of Talent Sourcing and Staffing

Corporate Recruitment & Title 38 Branch

Scientific Staffing & Outreach Branch

Customer Care and Data Quality Branch

DCO. ORGANIZATION. The Office of Policy, Legislation, and International Affairs is headed by the Deputy Commissioner for Policy, Legislation, and International Affairs and includes the following organizational units:

OFFICE OF POLICY, LEGISLATION, AND INTERNATIONAL AFFAIRS

Intergovernmental Affairs Staff

Management and Operations Staff

Office of Congressional Appropriations

Office of Economics and Analysis

Office of Global Policy and Strategy

Office of Global Diplomacy and Partnerships

Office of Global Operations

Regional Field Office, China Office

Regional Field Office, Europe Office

Regional Field Office, India Office

Regional Field Office, Latin America Office

Office of Trade, Mutual Recognition and International Arrangements

Office of Legislation

Office of Policy

Policy Engagement and Coordination Staff

Regulations Editorial Staff

Regulations Policy and Management Staff

DCP. ORGANIZATION. The Office of the Chief Scientist is headed by the Chief Scientist and includes the following organizational units:

OFFICE OF THE CHIEF SCIENTIST

Advisory Committee Oversight and Management Staff

Office of Counter-Terrorism and Emerging Threats

Office of Laboratory Safety

Office of Regulatory Science and Innovation

Office of Scientific Integrity

Office of Scientific Professional Development

National Center for Toxicological Research

DCQ. ORGANIZATION. The Office of Women's Health is headed by the Assistant Commissioner for Women's Health and includes the following organizational units:

OFFICE OF WOMEN'S HEALTH

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide. Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at:

<https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>

(Authority: 44 U.S.C. 3101).

Alex M. Azar, II,

Secretary, HHS.

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